

Organ Donation

Task 2: Assess current policies and the potential impact of the Final Rule on organ donation rates, the reasons for differences in organ donation rates and the impact of broader sharing (that is, based on medical criteria instead of geography), on donation rates.

Abstract. Many factors unrelated to the size of organ allocation areas affect organ donation rates. Based on the limited data available, the committee found no convincing evidence to support the claim that broader sharing would adversely affect donation rates or that potential donors would decline to donate because an organ might be used outside the immediate geographic area. In fact, there is some evidence suggesting that broader sharing is associated with increased rates of donation, although the reasons for this are not clear. Regardless of the impact of the size of the allocation area on donation rates, current efforts to increase donation seem to be having a positive effect and should be encouraged to continue.

The organ procurement and transplantation process begins at the hospital when a patient is identified as a potential organ donor. Most donated organs come from patients who are pronounced brain dead as a result of disease or injury, most notably, brain hemorrhage and injuries from motor vehicle crashes, gunshot or stab wounds, or asphyxiation (UNOS, 1999). Once a potential donor has been identified, someone from the hospital or an organ procurement organization (OPO) typically contacts the donor's family. If the family consents to donation, OPO staff coordinates the rest of the procurement activities, from organ recovery and preservation to transport to a transplant center for transplantation. The system by which organs are procured and transplanted includes many participants, including the family of the organ donor, the procuring surgeon, the OPO, the Organ Procurement and Transplantation Network (OPTN) operated by the United Network for Organ Sharing (UNOS), the transplant surgeon, the hospital staff, and the organ recipient.

The task of the committee with regard to organ donation was to determine what impact current allocation policies might have on organ donation rates and to assess the potential consequences of broader sharing of organs in larger geographic areas. The committee was not charged with solving the problem of the need for more donation, but instead, with determining the factors affecting donation that might be influenced by the Final Rule. This task is difficult because of the many elements that affect donation and the limited amount of published literature on this subject.

Among the many factors affecting donation are donor family motivation and OPO procurement practices, both having potentially significant influence on the number of organs actually recovered. Thus, for example, a highly motivated family might not be approached in a health care facility that does not actively pursue organ procurement. Conversely, ambivalent or unaware potential donor families could be persuaded to donate by health care providers trained in the appropriate procedures for actively pursuing organ procurement. Trying to parse out the relative contributions of donation versus procurement to organ availability rates is complex and few reliable data exist documenting the relative effects of either factor. To attribute any one factor—for example, local allocation policies—to potential changes in donation rates is overly simplistic.

Yet a central issue for opponents of broader sharing is that it will reduce organ donation because people will be less motivated to donate if the organs are not used locally. They also claim that health professionals will be less motivated to procure organs, knowing that they will not necessarily be used locally. Proponents of broader sharing argue that the changes in policy will not adversely affect donation rates because people are not motivated to donate for the purpose of local use.

CURRENT STATUS

Despite the increasing numbers of patients in need of organ transplantation, its potential to save lives is limited by the shortage of suitable organs for transplantation. National estimates of the number of potential organ donors vary widely, from 5,000 to 29,000 (Association of Organ Procurement Organizations, 1997; UNOS, 1998). In 1996 the number of medically suitable potential donors was estimated at 13,700 (Gortmaker et al., 1996), and in 1997 a review of medical records in hospitals in four regions of the United States estimated the pool to be between 12,000 and 15,000 annually (McNamara et al., 1997). Given that there were almost 5,800 cadaveric donors in 1998, these studies suggest that less than half of the nation's donor potential is currently being realized (McNamara and Beasley, 1997). Living donation is an additional option for centers that wish to increase the number of some solid organ transplant procedures (primarily kidney, although in some cases liver or lung).

In mid-April 1999, the U.S. Department of Health and Human Services (DHHS) and the United Network for Organ Sharing (UNOS) announced preliminary data showing that cadaveric donations increased 5.6 percent from 5,478 donors in 1997 to 5,794 donors in 1998, the first substantial increase since 1995 (DHHS, 1999a). Although donors increased in all age ranges, the greatest increase was among older donors. Donors age 60 or older increased by 10.8 percent; donors ages 40 to 59 increased by 9.6 percent; those ages 20 to 39 increased by 2.4 percent; and donors under age 19 increased by only 1.6 percent.

Rates of donation differed among racial and ethnic groups. There were substantial increases in the number of Caucasians (up 6.6 percent) and Hispanics

(up 7.8 percent), but for this one year time period, the number of African American donors remained relatively unchanged and the number of Asian donors decreased by 8.4 percent (DHHS, 1999a). Interestingly, donation rates increased in areas of the country that participate in broader sharing of organs (UNOS Regions 10, 8, and 4) although the meaning of this is unclear (DHHS, 1999a).

Although some of these data show promising upward trends, the number of donations is still far short of what is needed to meet the growing demand. Moreover, it is not clear how much of the overall increase in donations is due to a liberalization of donor criteria, to better public education and understanding, or to increased procurement efforts by hospital and OPO personnel.

In the same period that overall donation rates increased, waiting list registrations climbed substantially, from 56,716 to 64,423 (DHHS, 1999a). Thus, even if donation rates continue to increase, the demand will likely continue to outstrip the supply, necessitating careful attention to the issues of donation, equitable access, and allocation.

Correlates of Donation

As mentioned above, organ donation rates vary, in part, as a function of sociodemographic factors. These include cultural attitudes, the age and race of the donor, the progression of illness in the donor, the attitudes of the donor's family, the manner in which individuals are approached, and the policies and practices of hospital staff and organ procurement organizations (OPOs). For example, it appears that higher donation rates are achieved when requests are made by the staff of the OPO working with the patient's physician or nurse, rather than by hospital staff alone (Gortmaker et al., 1998). Involving medical social workers and clergy also has a positive influence on rates of consent for donation (Siminoff et al., 1995).

Age and race are also associated with rates of donation. The families of potential donors who are less than 50 years old are five times more likely to agree to donate organs than families of potential donors over 60, although this difference may be due in large part to the way the families are approached and information is provided, rather than being a direct function of the age of the patient (Gortmaker et al., 1996).

Organ donation is not as common in the African American community as it is in others. In a study comparing African Americans and whites (see also Chapter 3), it was suggested that African Americans may be only half as likely to donate as whites, because they are less likely to be asked, and because health care professionals do not ask them for consent in an effective way (Ehrle et al., 1999; Gortmaker et al., 1996; Randall, 1996). Another reason for lower donation rates within the African American community may be distrust of the system that stems in part, from reports such as those that report African Americans with end-stage renal disease are more likely to wait longer, less likely to receive a

transplant, and have less successful posttransplant outcomes than whites (Eggers, 1995; also see Gaylin et al., 1993; Held et al., 1988; Kallich et al., 1990; Kjellstrand, 1988; Sanfillippo et al., 1992). Knowledge and perceptions about these racial disparities affects the attitude towards organ donation in the African American community (Kasiske et al., 1991).

PUBLIC AND PROFESSIONAL ATTITUDES

There are few data available to determine with confidence the effects of organ allocation policies on donation rates. However, a July 1998 Gallup Poll conducted for the National Transplant Action Committee examined adults' attitudes toward organ allocation policies and their effects on organ donation (Gallup Organization, Inc., 1998). The study found that 75 percent of respondents reported it would make no difference in their decision to donate to know that the organ would go to a more seriously ill person elsewhere in the United States before being offered to a less sick person within the local region (see Box 4-1).

Another poll conducted by Southeastern Institute of Research (1994) reported similar findings. Respondents who were not donor card signers were asked which of two policies would have the strongest influence on their becoming an organ donor: one that keeps organs locally for local patients or one that ships organs nationally for all patients. Only 19 percent said that the local policy would have the strongest influence; 66 percent chose the national policy; and 13 percent said neither policy would influence them.

BOX 4-1 Excerpt from the 1998 Gallup Poll on Organ Donation

Question 4: "Thinking as if you were going to be an organ donor, if you learned that your organs would go to sick persons within your local region before they were offered to sicker persons elsewhere in the U.S. would you be more likely to want to donate, less likely to want to donate, or would it not matter in your decision."

In response, the report states: "... most adults say it would not affect their decision. However, 32% say if they knew the organ recipient was the sickest person, regardless of location, they would be more likely to donate an organ. In contrast, 10% would be more likely to donate if they knew their organ was going to a sick person in their local region. It may also be noted that those who have signed an organ donor card, are recipients or candidates for an organ, or have donated an organ or bone marrow are most inclined to say the location of a potential organ recipient would not affect their decision to donate."

SOURCE: Gallup Organization Inc., 1998

As stated in the preamble to the Final Rule, “DHHS has seen no credible evidence that local preference encourages donation or that sharing organs regionally or nationally for the sickest patients will impact organ donation. Nor is there any evidence that transplant professionals perform differently when the retrieval is for a distant patient rather than a local patient” (DHHS, 1998b).

Testimony presented to the committee during the public meeting on April 16, 1999, by representatives from community hospitals supported this view, indicating that health professionals at the bedside are not aware of the destination of a procured organ and do not consider this in performing their duties. Others voiced opinions that some families of potential donors would not agree to donate if the organs were sent out of state. Most agreed, however, that families want organs to go to the patients most in need, preferably within the state, but within a broader region if this is where the most medically urgent patient is located.

Finally, preliminary data on organ donation rates seem to bear out the notion that local use does not necessarily improve donation rates. Although, as shown in Tables 4-1 and 4-2, the overall number of cadaveric donors rose in 1998 by approximately 6 percent, the largest increase (13 percent) occurred in UNOS Region 10 (Michigan, Indiana, and Ohio) (DHHS, 1999a; UNOS, 1999)—a region that recently instituted a voluntary regional sharing arrangement for livers. Other large increases occurred in Region 8 (Iowa, Missouri, Nebraska, Kansas, Wyoming, and Colorado)—11.3 percent—and in Region 4 (Oklahoma and Texas)—9.1 percent (DHHS, 1999a; UNOS, 1999). Each of these regions engages in broader sharing beyond the local OPO service area.

Need for Educational Interventions

While the consent rate for potential organ donors from African American families continues to be less than that of white families (Eckhoff et al., 1998), there are data demonstrating that a concerted effort to increase donation can be, and has been, quite successful. Between 1988 and 1996, organ donation among African Americans increased from 17 to 23 percent (Ehrle et al., 1999; UNOS, 1998), largely because of innovative programs that target the needs of minority populations with interventions such as race-specific requesters (Ehrle et al., 1999; First, 1997; Gentry et al., 1997; Kappel et al., 1993). Within this same time frame, the OPO for the University of Alabama at Birmingham was able to increase its organ donation rates from 6.1 percent to 21.9 percent (Eckhoff et al., 1998). This increase in donation was accomplished by improving the awareness by transplant coordinators about cultural differences and by hiring minorities for outreach and coordinator positions. Nevertheless, still more can be done on a national level to improve these statistics.

TABLE 4-1 Number of Cadaveric Donors by Donor Age from 1994 through October 31, 1998

Donor Age	Year Donor Recovered											
	1994		1995		1996		1997		1998		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Not reported	15		28		81		153		309		586	
<1	94	1.8	86	1.6	73	1.4	100	1.9	98	1.8	451	1.7
1-5	203	4.0	214	4.0	189	3.5	214	4.0	226	4.1	1,046	3.9
6-10	166	3.3	181	3.4	160	3.0	147	2.8	150	2.7	804	3.0
11-17	683	13.4	706	13.2	620	11.6	585	11.0	560	10.2	3,154	11.9
18-34	1,545	30.4	1,539	28.9	1,479	27.7	1,440	27.0	1,437	26.2	7,440	28.0
34-49	1,237	24.3	1,304	24.5	1,390	26.0	1,355	25.4	1,426	26.0	6,712	25.3
50-64	933	18.3	1,027	19.3	1,081	20.3	1,102	20.7	1,124	20.5	5,267	19.8
≥65	224	4.4	276	5.2	346	6.5	382	7.2	464	8.5	1,692	6.4
Total	5,100	100.0	5,361	100.0	5,419	100.0	5,478	100.0	5,794	100.0	27,152	100.0

SOURCE: Based on UNOS/OPTN (1999) Scientific Registry data as of May 22, 1999.

TABLE 4-2 Number of Cadaveric Donors by Donor Race from 1994 through October 31, 1998

Donor Race	Year Donor Recovered											
	1994		1995		1996		1997		1998		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Not reported	2		19		74		142		297		534	
White	3,972	77.9	4,129	77.3	4,096	76.6	4,030	75.5	4,198	76.4	20,425	76.7
African American	585	11.5	609	11.4	647	12.1	629	11.98	609	11.1	3,079	11.6
Hispanic	418	8.2	485	9.1	488	9.1	549	10.3	574	10.4	2,514	9.4
Asian	93	1.8	80	1.5	84	1.6	99	1.9	92	1.7	448	1.7
Other	30	0.6	39	0.7	30	0.6	29	0.5	24	0.4	152	0.6
Total	5,100	100.0	5,361	100.0	5,419	100.0	5,478	100.0	5,794	100.0	27,152	100.0

SOURCE: Based on UNOS/OPTN (1999) Scientific Registry data as of May 22, 1999.

In testimony to the IOM committee on April 16, 1999, it was stated that donor shortage is, in part, a result of perceived inequities in organ allocation (Callender, 1999). The shortage exists in all communities, but especially in the African American. To address this problem, it was suggested that there must be a focus on the impediments to donation, which include:

- the perception of inequitable organ allocation;
- suboptimal use of the community as a change agent for organ tissue donation and transplantation;
- lack of involvement of the community at all levels of problem resolution, research, and resource allocation;
- lack of transplantation awareness;
- religious myths and misperceptions;
- distrust of the health care system and health care professionals;
- fears that signing donor cards will lead to premature declaration of death;
- inadequate use of recipients, donors, and transplant candidates as community messengers; and
- inadequate allocation of funds for donation education efforts.

The example of lower rates of organ donation in the African American community helps illustrate that variability in organ donation rates is due to many causes. There is no evidence available to suggest that local allocation policies alone would significantly alter donation rates. It is more likely that enhanced educational interventions at the public and professional levels would significantly alter participation in the system, along with public policies that encourage donation. Some of these (i.e., “required request,” “routine verification,” and other approaches to improve donation) are described in the following section.

REQUIRED REQUEST AND ROUTINE NOTIFICATION

By the late 1980s, most states and the District of Columbia had enacted “required request” legislation in an effort to increase hospital referral rates. This legislation requires hospitals to consult with the potential donor’s next of kin and specifically request organ donation should the patient be at, or near, death (American Hospital Association et al., 1988; Cate and Laudicina, 1991). In some instances, hospitals may be required to refrain from asking family members to consent if: the patient is medically unsuitable, there are contrary indications from the family, there are conflicting religious beliefs from either the family or potential donor, the family is too emotionally traumatized to be consulted for donation, or prior objections to organ donation have been made by the patient (American Hospital Association et al., 1988; Ehrle et al., 1999). However, several studies by the Partnership for Organ Donation and the Harvard School of Public Health have shown that more than one-quarter of the time, eligible families are not even offered the option to donate (Gortmaker et al., 1996).

The 1986 Omnibus Reconciliation Act (42 U.S.C. 1320b-8) required hospitals to have processes in place to ensure that all families of potential donors are identified and referred to the OPO and that all families are given the opportunity to consent or decline to donate the organs of their relative. The law authorizes Medicare and Medicaid funds to be withheld from hospitals that did not comply, but this authority has never been exercised.

“Required request” legislation, on both the state and national levels, did not appear to contribute to a substantial increase in donation. In continuing the effort to increase donation, several states, led by Pennsylvania, have passed “routine notification” legislation to address the problem of failure to determine which patients are potential donors (Ehrle et al., 1999). This legislation requires that all deaths or deaths that are imminent within a hospital be referred to the Medicare-certified OPO. In other areas of the United States, hospitals and OPOs have voluntarily adopted a policy of routine notification (Ehrle et al., 1999).

Reports from an OPO in Pennsylvania indicated substantial increases in organ as well as tissue and eye donations in the 3 years since implementation of routine notification (Ehrle et al., 1999). The Delaware Valley Transplant Program,* which serves Delaware, southern New Jersey, and the eastern half of Pennsylvania, reported a 49 percent increase in donations since 1994 when Pennsylvania passed its comprehensive law governing organ donation (Nathan, 1998).

An OPO in Texas, a state that does not have routine notification laws, worked with its hospitals to voluntarily implement routine notification and experienced a 12 percent increase in organ donation in the 2 years after implementation, an increase that was 352 percent greater than the national growth in organ donation (Ehrle et al., 1999; Shafer et al., 1998).

At the federal level, in June 1998 the Health Care Financing Administration (HCFA) issued an amendment to its *Hospital Conditions of Participation for Medicare and Medicaid*, which requires all acute care hospitals to notify their local OPO of all hospital deaths (Ehrle et al., 1999). The OPO could then request donation from families of potential donors. If followed consistently, it appears that this policy of routine notification would substantially increase the number of potential organ donors referred to OPOs (Ehrle et al., 1999).

Additional Approaches to Improve Donation

Health professionals and patient groups concerned with the low rate of organ donation have suggested additional approaches to increase donation. These have included development of standardized hospital practices; improvement of the consent process; better training of medical staff; refocusing public education to promote family discussion; and clearer guidance about brain death for fami-

* The Delaware Valley Transplant Program recently changed its name to Gift of Life Donor Program (Gift of Life Donor Program, 1999).

lies and health professionals (Dejong et al., 1995; Franz et al., 1997; Gortmaker et al., 1996; McNamara and Beasley, 1997). Other efforts to promote donation include public awareness campaigns, efforts by local OPOs nationwide to address donation at the community level, and projects conducted by national groups to educate health professionals and the public about donation and transplantation. In addition, donor criteria have been expanded to allow older and less healthy patients to donate organs.

A controversial method to encourage organ donation has been recently proposed in Pennsylvania. If adopted, this program will help defray the organ donor's family funeral expenses by providing \$300 from a special state fund directly to the funeral home that handles the donor's burial arrangements (Nathan, 1999). Advocates of this law argue that this program is not established as a payment for organs because the law requires that any payment be made directly to the funeral home and not to the donor's family, next of kin, or estate (La Hay, 1999; Pennsylvania Act 1994-102, 1994). Rather, the intent of this pilot program is to increase awareness and participation in organ donation.

ASSESSING OPO PERFORMANCE

A major impediment to greater accountability and improved performance on the part of OPOs is the current lack of a reliable and valid method for assessing donor potential and OPO performance (Christiansen et al., 1998). HCFA currently evaluates OPO performance (on a per-million population basis) for the following performance measures: (1) organ donors; (2) kidneys recovered; (3) kidneys transplanted; (4) extrarenal organs recovered (heart, liver, pancreas, lungs); and (5) extrarenal organs transplanted. Each OPO must meet numerical goals in at least four of the five categories to be recertified by HCFA as the OPO for a particular area and to receive Medicare and Medicaid payment. Without HCFA certification, an OPO cannot continue to operate.

In 1997 the U.S. General Accounting Office (GAO) determined that the current performance measures do not accurately assess OPO performance because they are based on total population, not the number of potential donors (GAO, 1997). OPO service areas vary widely in the distribution of deaths by cause, underlying health conditions (e.g., HIV, liver disease), age, and race, which in turn affect the number of potential donors. The GAO identified four alternative performance measures that would better estimate the number of potential organ donors: organ procurement and transplantation compared with the number of deaths, deaths adjusted for cause of death and age, medical records reviews, and modeling (GAO, 1997). HCFA is currently evaluating the feasibility and usefulness of implementing revised measures.

Although efforts are underway to use a denominator that more accurately identifies potential donors, other performance criteria are needed for OPOs, (e.g., measures of the quality, function, and biological outcomes of the trans-

planted organs), rather than depending solely on donors per population or donors per hospital death.

CONCLUSIONS

Many variables affect organ donation rates, including cultural attitudes, the age and race of the donor, the progression of illness in the donor, the attitudes of the donor's family, the manner in which individuals are approached, and the policies and practices of hospital staff and organ procurement organizations. The most important way to increase donation is to ensure that all eligible families are approached about donation.

Based on a review of the literature and survey data, testimony received, and preliminary data on increased donation rates in UNOS regions that engage in broader sharing beyond the local OPO service areas, the committee concludes that organ donation rates are not likely to be affected adversely by broader sharing (i.e., allocation areas that exceed the geographic boundaries of the OPO). To address the continuing concerns about donation, the committee believes that concerted efforts among health professionals involved in organ procurement should continue—including development of standardized hospital practices; improvement of the consent process; better training of medical staff; refocusing public education to promote family discussion; and clearer guidance about brain death for families and health professionals. These activities and relationships of the OPO are necessary components of effective organ donation activities that should not be affected by broader allocation policies.